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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

[30Day-13-12PZ]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Proficiency Testing in US Clinical Laboratories: Perception, Practices and Potential for Expanded Utility - NEW - The Office of Surveillance, Epidemiology and Laboratory Services (OSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The primary focus of this project is to conduct a systematic analysis in order to understand which types of laboratories follow Proficiency Testing (PT) and Good Laboratory Practices (GLPs), to identify ways that PT and GLPs could be better promoted, and to identify populations that would benefit from receiving information on PT GLPs. The Association of Public Health Laboratories (APHL) and Centers for Disease Control and Prevention (CDC) hope to learn more about the perceived benefits and burden of performing PT. This information may be helpful to the CDC as the Clinical Laboratory Improvement Amendments (CLIA) regulations for PT are revised. Our survey population frame is 20,500 Certificate of Compliance laboratories and 16,800 Certificate of Accreditation laboratories. All of these laboratories are required to perform PT in accordance with CLIA. Many of these laboratories also use their PT results internally to further improve laboratory quality at no additional cost.

The first phase of this project was conducted by the APHL through focus group research in 2011. The research explored how clinical and public health laboratories perceived commercial PT programs and explored the ways in which the laboratories used PT to assure and improve the quality of their testing. This second phase of the project will be administration of a survey to build

on the preliminary findings from the focus group research and help identify the types of laboratories that would benefit from learning about additional uses for PT. This information will be helpful to disseminate PT and GLPs to laboratories in a strategic and targeted way based on findings from this survey.

The goal is to achieve an 80% response rate (29,840 out of 37,300 laboratories). APHL and CDC will strive to ensure a high response rate by promoting the survey through advertisements in laboratory trade publications, at professional meetings, and possibly through programs and laboratory accreditation organizations.

The cohort of laboratories surveyed will be all Certificate of Compliance and Certificate of Accreditation laboratories listed in the Centers for Medicare and Medicaid Services (CMS) Online Survey, Certification and Reporting (OSCAR) database. The OSCAR database contains demographic information and relevant characteristics including laboratory specialty and laboratory type for each laboratory.

The survey will be administered through a web-based survey system, specifically Survey Monkey. APHL will send each laboratory a postmarked letter explaining the survey and provide

them with a link to log in to the survey with a unique identifier on their address label. Two weeks afterwards, APHL will follow-up with a postcard reminder which will also include that unique identifier.

There are no costs to respondents other than their time.

The annualized estimated burden is 9,947 hours.

Estimated Annualized Burden Hours:

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hrs)
Laboratorians	Laboratory Practices	29,840	1	20/60

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